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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,795	01/03/2002	John A. Krueger	SPEC - 6137	6948

7590  
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EXAMINER
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FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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03/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/037,795	<b>Applicant(s)</b> KRUEGER, JOHN A.	
	<b>Examiner</b> JONATHAN ML FOREMAN	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 9/20/07. Accordingly, the following action has been made Non-Final.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 7 – 16 and 18 – 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,513,754 to Lee in view of U.S. Patent No. 5,385,561 to Cerny.

In regards to claims 7 – 11, 15, 16 and 18 – 22, Lee discloses a bone biopsy system including an outer cannula (24') defining a length from a proximal end to a beveled distal tip; a handle portion (18") coupled to the proximal end of the outer cannula; the outer cannula is adapted to removably accommodate a biopsy aspiration device (102) therein. The aspiration device includes an elongated cannula body (102) having a proximal end (108), a distal tip (105) and a linear longitudinal axis, wherein the length of the elongated cannula is greater than the length of the outer cannula; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal opening (Col. 5, line 55) adjacent to the tip. Lee discloses an outer cannula hub connected to a proximal portion of the outer cannula; and an inner cannula hub (108) connected to the proximal end of the elongated cannula body; wherein the hubs are configured to establish a substantially air tight seal upon assembly (Col. 5, lines 60 – 65). The

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proximal end of the cannula body comprises a luer attachment (114, 116) for removable coupling of an aspiration source. Lee discloses a stylet (104) for removable insertion within the outer cannula (Figure 9). Lee discloses viewable indicia indicating the position of the distal opening (Col. 5, lines 65 – 68). However, Lee fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening. However, Cerny discloses an elongated cannula body (14) having a proximal end, a distal tip (20) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body, the lumen terminating at a proximal opening and terminating at a single laterally oriented distal opening (24) immediately adjacent the distal tip; wherein the tip of the cannula body comprises an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening (Figures 2A and 2B). It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as disclosed by Lee to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Cerny in order to penetrate the tissue without coring (Col. 7, lines 36 – 38).

In regards to claims 12 – 14, Lee discloses a method for obtaining a bone marrow sample from a marrow site in a patient including penetrating the cortex of a bone with an outer cannula having a stylet positioned within (Col. 6, lines 25 – 27), the distal portion of the stylet extending beyond the end of the outer cannula, until the distal end is surrounded by marrow; removing the stylet (Col. 6, lines 28 – 29); inserting into the outer cannula a biopsy aspiration device such that the distal tip of the aspiration device is extended into marrow (Col. 6, lines 25 - 27). Lee discloses attaching an aspiration source to the proximal end of the aspiration device and withdrawing a sample

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of marrow from the sampling site (Col. 6, lines 29 - 31). Lee discloses removing the aspiration device from the outer cannula and advancing the outer cannula into the bone to obtain a core sample (Col. 6, lines 36 - 39). Lee discloses the aspiration device including an elongated cannula body (102) having a proximal end (108), a distal tip (105) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal opening (Col. 5, line 55) adjacent to the tip. However, Lee fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening. However, Cerny discloses an elongated cannula body (14) having a proximal end, a distal tip (20) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body, the lumen terminating at a proximal opening and terminating at a single laterally oriented distal opening (24) immediately adjacent the distal tip; wherein the tip of the cannula body comprises an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening (Figures 2A and 2B). It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as taught by Lee to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Cerny in order to penetrate the tissue without coring (Col. 7, lines 36 - 38).

### ***Response to Arguments***

3. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736